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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,944	12/12/2003	Jong Kil	A03P1079US02	3701

36802 7590 11/27/2006

PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 11/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/735,944

Applicant(s)

KIL ET AL

Examiner

George R. Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/7/06 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 and 7-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Hedberg et al (5740811). Hedberg shows in figures 1 and 2 the use of a single cardiac signal as cross chamber sensing (as IEGM diff, 33) for the surface EKG, shows in figure 9 the cross chamber sensing (tip-can+SVC-can) with the resulting emulated surface EKG, and states that the synthesized ECG can use any combination of electrodes (columns 6 and 8). In addition, Hedberg distinguishes portions and identifies transitions related to the atrial signals from those corresponding to the ventricular signals and adjusts the relative amplitudes of the portions corresponding to atrial and ventricular signals as seen in column 5, lines 38-52 using non-linear

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amplification, column 8, line 53-column 10, line 51, the description of figure 13 of using different weightings/scaling factors for the signal amplitudes corresponding to different atrial and ventricular signals/locations and the use of a neural network being trained with a surface ECG to adjust the cross chamber IEGM (columns 5 and 6) and therefore inherently adjusts the amplitudes of the atrial and ventricular signals since the signal is processed to be similar to the training surface ECG. Specifically, Hedberg shows an example in figure 5A and 5B of a single V tip to can cardiac signal and the use of non-linear amplification to adjust relative amplitudes of the atrial and ventricular signal to produce an emulated surface EKG showing the P wave, R wave, and T wave. Although this is a unipolar signal, this is Hedberg's example of how the atrial and ventricular signals can be distinguished and adjusted. In addition, Figure 9 shows the cross chamber single cardiac signal and corresponding emulated surface EKG. For claims 2 and 3, since the system is trained with a surface ECG, uses non-linear amplification, and weightings/scaling factors, the system possesses a predetermined ratio, such as 1:4 to 1:10 (in the alternative, see the 103 rejection below for claim 3), since this is the ratio of a normal ECG. For claim 7, Hedberg discusses controlling the pacer or defibrillator with the synthesized ECG in columns 7 and 8, lines 1-10 and 10-14, respectively. For claims 8 and 9, Hedberg discusses the use of the IMD or an external device performing the adjustments/synthesizing in column 3, lines 1-13.

It is noted that Hedberg also uses several single cardiac signals, such as unipolar and cross chamber signals, and adjusts relative amplitudes of the atrial and ventricular signals (as discussed above) to produce an emulated surface EKG. It is also noted that the claim is a "comprising" claim, an open ended claim, and does not preclude the use of emulating the surface

EKG from several single cardiac signals (the claim does not say, "to yield an emulated surface EKG using only the single cardiac signal).

Claims 1-5 and 7-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Kroll et al (6813514). Kroll describes in columns 16 and 17 the use of cross chamber sensing. In addition, Kroll distinguishes portions and identifies transitions related to the atrial signals from those corresponding to the ventricular signals and adjusts the relative amplitudes of the portions corresponding to atrial and ventricular signals as seen, for example, in column 20, lines 30-32, column 20, line 47 to column 21, line 10, column 22, lines 20-30, and column 26, line 55-column 27, line 20. Since Kroll's cross chamber signal is a voltage signal and since Kroll uses weighting factors to affect the voltages (col 19, lines 45-62) he will adjust the relative amplitudes corresponding to atrial and ventricular signals. In addition, Kroll trains his system with a surface ECG to adjust the cross chamber IEGM (columns 24-27) and therefore inherently adjusts the amplitudes of the atrial and ventricular signals since the signal is processed to be similar to the training surface ECG. For claims 2 and 3, since the system is trained with a surface ECG, the system possesses a predetermined ratio, such as 1:4 to 1:10 (in the alternative, see the 103 rejection below for claim 3) since this is the ratio of a normal ECG. For claim 5, Kroll identifies the ventricular depolarization and repolarization using the baseline as transition points (see figure 8). For claim 7, Kroll discusses controlling the IMD with the synthesized ECG in column 18, lines 51-65. For claims 8 and 9, Kroll discusses the use of the IMD or an external device performing the adjustments/synthesizing in column 4, lines 44-50.

It is noted that Kroll uses several single cardiac signals, such as unipolar and cross chamber signals, and adjusts relative amplitudes of the atrial and ventricular signals (as discussed above) to produce an emulated surface EKG. It is also noted that the claim is a “comprising” claim, an open ended claim, and does not preclude the use of emulating the surface EKG from several single cardiac signals (the claim does not say, “to yield an emulated surface EKG using only the single cardiac signal).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hedberg et al (or for claims 3 and 6 over Kroll et al).

Hedberg or Kroll discloses the claimed invention except for predetermined ratio being 1:4 to 1:10, the use of the baseline before the depolarization/repolarization as transition points, and the use of the baseline before the depolarization as the transition point and a preceding R-R interval and time delay to identify a second baseline point for the transition point. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ECG synthesizing system and method as taught by Hedberg or Kroll, with the predetermined ratio being 1:4 to 1:10, the use of the baseline before the depolarization/repolarization as transition points, and the use of the baseline before the depolarization as the transition point and a preceding R-R interval and time delay to identify a second baseline point for the transition point since: it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (*In re Aller*, 105 USPQ 233); it was known in the art that ECG systems use the baseline before the depolarization/repolarization as transition points as conventional ways to effortlessly determine the depolarization/repolarization phases of the cardiac cycle; and the use of the baseline before the depolarization as the transition point and a preceding R-R interval and time delay to identify a second baseline point for the transition point to easily determine the depolarization phase of the cardiac cycle and to conventionally estimate the repolarization phase of the cardiac cycle since the repolarization phase is of lower amplitude and sometimes hard to detect.

Double Patenting

Claim 1 of this application conflicts with claim 6 of Application No. 10/736111. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the

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absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822. Since claim 6 of 10/736111 contains all the limitations of claim 1 of this application, the claims contain the same limitations.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6, and 8-16 of copending Application No. 10/736111. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application's claims are more narrow and meet the limitations of this application's claims. In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the copending application's claims the step/element of sensing cross chamber signals, using the baseline prior

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to the depolarization/repolarization, or using the baseline before the first R wave as the depolarization transition point and the preceding R-R interval and time delay to find the transition point for the repolarization since it provides a better signal representing the appearance of a surface ECG and provides more and different information to determine arrhythmias, since the baseline prior to the depolarization/repolarization is known to be the transition point in the ECG to simply determine the specific cardiac phases, and since the preceding R-R interval and time delay are used to determine the transition point for the repolarization to easily determine the repolarization phase since the repolarization is difficult to detect due to its small amplitude.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 11/7/06 have been fully considered but they are not persuasive. The argument that Hedberg or Kroll use signals from two or more intracardiac electrodes and do not adjust relative portions of a "single cardiac signal" and that Kroll teaches away from "using a single cardiac signal to derive information pertaining to atrial and ventricular signals" is not persuasive. In regards to Hedberg, Hedberg shows specifically in figures 5 and 9 the use of single cardiac signals (unipolar and cross chamber) and the resulting emulated surface electrogram. In addition, Hedberg shows in figures 1 and 2 the use of a single cardiac signal as the output of the differential amplifier. Although Hedberg may state in column 2 that the term synthesized ECG means a signal generated from at least two in vivo signals, "such as" at least two IEGMs, Hedberg specifically shows the use of single cardiac signals to produce the

emulated surface electrogram (e.g. figures 5, 9, 1, and 2). In addition, receiving a cross chamber signal is receiving two in vivo signals, one from the atrium and one from the ventricle.

In regards to Kroll, Kroll distinguishes portions and identifies transitions related to the atrial signals from those corresponding to the ventricular signals and adjusts the relative amplitudes of the portions corresponding to atrial and ventricular signals as seen, for example, in column 20, lines 30-32, column 20, line 47 to column 21, line 10, column 22, lines 20-30, and column 26, line 55-column 27, line 20. Since Kroll's cross chamber signal and atrial unipolar signals are a voltage signal and since Kroll uses weighting factors to affect the voltages (col 19, lines 45-62) he will adjust the relative amplitudes corresponding to atrial and ventricular signals. In addition, Kroll trains his system with a surface ECG to adjust the cross chamber IEGM and unipolar IEGM (columns 24-27) and therefore inherently adjusts the amplitudes of the atrial and ventricular signals since the signal is processed to be similar to the training surface ECG. Although Kroll may state in column 21 that ventricular electrodes are better for ventricular signals and atrial signals are best constructed from atrial electrodes, that particular portion of the specification does not state that atrial signals are not used from the ventricular electrodes or that ventricular signals are not used from the atrial electrodes.

Finally, it is noted that Kroll and Hedberg also use several single cardiac signals, such as unipolar and cross chamber signals, and adjust relative amplitudes of the atrial and ventricular signals (as discussed above) to produce an emulated surface EKG. It is also noted that the claim is a "comprising" claim, an open ended claim, and does not preclude the use of emulating the surface EKG from several single cardiac signals (the claim does not say, "to yield an emulated

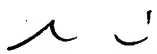
surface EKG using only the single cardiac signal--although this limitation will need to be further considered and may be new matter).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


George R Evanisko
Primary Examiner
Art Unit 3762

11/19/06

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